JUN 1 4 2013

510(k) SUMMARY

Submitter's Name and Address	DePuy Mitek *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767
Contact Person	Tatyana Korsunsky Regulatory Affairs Specialist DePuy Mitek, Inc. *a Johnson & Johnson company* 325 Paramount Drive Raynham, MA 02767, USA Telephone: 508-828-3122 Facsimile: 508-977-6911 e-mail: tkorsuns@its.jnj.com
Name of Medical Device	Proprietary Name: OMNICUT™ Resection Blade Common Name: Blade
Substantial Equivalence Facility	The OMNICUT™ blades are substantially equivalent to: • K953695: Dyonics Disposable Arthroscopic Blades (Full Radius Bonecutter blade) • K954465: FMS DUO® pump and shaver system (FMS blades) • K041824: FMS NeXtra™ arthroscopic pump and shaver system (FMS blades)
Device Classification	Classification Name: Arthroscope Classification Number: 21 CFR 888.1100 Class II Product Code: HRX
Device Description	OMNICUT Blades are used with FMS™ Handpieces and Fluid Management Systems during arthroscopic surgery. OMNICUT Blades consist of stainless steel outer tube and a rotating inner tube connected to an inner and outer plastic hubs. Distal tips of the tubes contain sharp edges to facilitate the cutting.
Indications for Use	The FMS Blades and Burrs are an accessory to the FMS Fluid Management Systems. FMS Blades and Burrs are intended to provide controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery.
Nonclinical Testing	Design verification activities, such as soft tissue and bone tissue removal, as well as blade particulate generation testing, were performed on OMNICUT blades and their predicate devices.
Safety and Performance	While there are no required tests for arthroscopy blades, the following preclinical studies were submitted to demonstrate substantial equivalence: 1. Blade soft tissue cutting comparison with K953695 predicate. 2. Blade bone cutting comparison with K953695 predicate. 3. Blade shed testing comparison with K953695 predicate. The OMNICUT blades passed all tests and showed equivalent performance.

	Results of performance and safety testing have demonstrated that the proposed devices are suitable for their intended use. Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed OMNICUT Blades have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.
Comparison to the predicate devices	The proposed OMNICUT Blades have the same intended use and are similar in design and materials to the predicate Smith & Nephew's Full Radius Bonecutter blades (K953695) and Mitek's FMS blades (K954465/ K041824). However, the proposed OMNICUT blades have a modified cutting window configuration and are provided lubricated. The proposed OMNICUT device can cut both bone and soft tissue, similar to a predicate Smith & Nephew's Full Radius Bonecutter blade.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

DePuy Mitek
% Ms. Tatyana Korsunsky
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130912
Trade/Device Name: OMNICUT Resection Blade
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: April 11, 2013
Received: April 12, 2013

Dear Ms. Korsunsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130912

Device Name: OMNICUT® Resection Blade

Indications for Use: The FMS Blades and Burrs are an accessory to the FMS Fluid Management Systems. FMS Blades and Burrs are intended to provide controlled cutting, burring, shaving and abrading of bone and tissue for use in arthroscopic surgery.

Prescription Use √ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

DSD—Division Sign-Off	
Division of Surgical Devices	Joshua C. Nipper -S
510(k) Number: K130912	